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July 14, 1999

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

RE: <u>Docket No. 99N-1393</u>: <u>Agency Information Collection Activities</u>: <u>Proposed</u>

Collection; Comment Request; State Petitions for Exemption from Preemption

We would like to take this opportunity to submit comments in response to the Food and Drug Administration's (FDA) recent notice, "Agency Information Collection Activities: Proposed Collection; Comment Request; State Petitions for Exemption from Preemption" (64 Federal Register 30037; June 4, 1999). Specifically, the Agency is requesting comments on the extension of reporting requirements contained in existing FDA regulations governing State petitions for exemption from Federal preemption, i.e., 21 CFR 100.1(d). The Association for Dressings and Sauces (ADS) is an international association of manufacturers of dressings for salads, mayonnaise, mustard and specialty sauces and their suppliers. ADS actively supports national uniformity, especially with respect to food labeling and standards of identity.

Section 403A of the Federal Food, Drug and Cosmetic Act (the Act) was enacted to maintain national uniformity. ADS supports the national uniformity intent of this section of the Act. However, under Section 403A(b) of the Act, States may petition FDA for exemption from Federal preemption of State food labeling and standard of identity requirements, and section 100.1(d) sets forth stringent requirements to be included in such a petition. ADS believes these requirements are necessary as it is important that any deviation from national uniformity be supported by strong and factual documentation. This will allow FDA to determine if the State's request complies with the statutory criteria for exemption from Federal preemption. ADS, therefore, supports retaining these requirements as an important part of implementing section 403A of the Act.

We noted with interest the Agency stated that few State exemption petitions for labeling requirements have been submitted. According to the notice, FDA has not received any exemption from preemption petitions over the past three years, and only eight such

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petitions have been received since enactment of section 403A of the Act as part of the Nutrition Labeling and Education Act of 1990. It is evident from the lack of petitions that the regulation and related statute are accomplishing the Congressional intent of maintaining national uniformity. Accordingly, there is no need to modify the current regulation, especially with respect to reporting requirements.

In conclusion, ADS strongly supports national uniformity and the maintenance of current regulations governing State petitions for exemption from preemption.

We appreciate the opportunity to submit these comments.

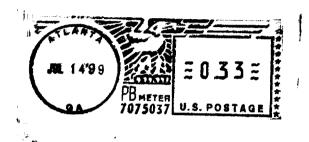
Respectfully Submitted,

Pamela A Chumley
Executive Director

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